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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

5

DATE MAILED: 01/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/891,691

Applicant(s)

HANSEN ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 13-18, 25 and 28-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 19-24, and 26-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: .

DETAILED ACTION

This application claims priority to provisional application Serial No. 60/173,959.

This application also claims priority to Denmark PA 2000 00987.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-27 drawn to a method for reducing the consumption of fat-containing food comprising a compound of the structural formula (I), classified in class 514, subclass 223.2, 438, and 444 for example.
- II. Claims 28-36 drawn to a method for reducing the consumption of fat-containing food comprising a potassium channel agonist, classified in class 514, subclass 223.2, 438, and 444 for example.

Group I and II are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are separate and distinct each from the other since Group I is drawn to a method for reducing the consumption of fat-containing food comprising a specified compound of the structural formula (I) herein whereas Group II is drawn to a method for reducing the consumption of fat-containing food comprising a potassium channel agonist. Therefore, Group I and Group II have different modes of operation.

The search for all inventions would place an undue burden on the Office in view of the diversity in the field of search for each.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention:

a plurality of disclosed patentably distinct compounds in Groups I-II (see above the restriction requirement), numerous active agents, for example, in claim 1

Applicant is required under 35 U.S.C. 121 to elect a single specified individual active compound to be employed in the claimed method in Group I-II for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-26 for Group I and claims 28-36 for Group II are generic to a plurality of disclosed patentably distinct species. The claims read on the employment of various compounds of the structural formula herein, with great diversity of chemical structure classified across class 514, the search for all of which presents an undue burden on the Office. It is noted that a reference to one individual agent would not be a reference to another individual agent under 35 U.S.C.103. The claims also read on numerous diseases or conditions to be treated.

A "specie" is a specific compound, with all parameters and/or substituent variables FULLY accounted for.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Ms. Reza Green on January 4, 2002 a provisional election was made with traverse to prosecute the invention of the species of claim 27 and the invention of Group I, claims 1-27. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 28-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 13-18 and 25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

The claims have been examined insofar as they read on the elected specie.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "from 10 kcal% fat" in claim 2 renders claim 2 indefinite. The expression "from 10 kcal% fat" is not understood in terms of the range of fat percentage. Therefore, the scope of claim is indefinite as to the fat-containing food encompassed thereby.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 19-24, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (US 5889002, WO 9726265, and WO 9903861, PTO-892) in view of Applicant's admission regarding the prior art (see pages 1-2).

Nielsen et al. (US 5889002) discloses that the active compounds represented by the general formula I therein which has covered the instant elected species are potassium channel openers and useful in a method of treating various diseases of the central nervous system and the cardiovascular system broadly, e.g., hypertension, heart disease, and diabetes. See abstract, col.1 lines 21-22, 45-50, col.2 lines 29 to col.7, col.13 lines 19-24. Nielsen et al. also teaches that potassium channel openers are also known to be useful in the treatment of obesity and decreasing weight gain. See col.2 lines 8-14. Nielsen et al. further discloses that the range of effective amounts of active compounds therein to be administered is within the instant range. See col. 18 lines 53-55.

Nielsen et al. (WO 9726265) discloses that the active compounds represented by the general formula I therein which has covered the instant elected species are potassium channel openers and useful in a method of treating various diseases of the central nervous system and the cardiovascular system broadly, e.g., hypertension, heart

disease, and diabetes. See abstract, page 1 lines 11, 16, 26-27, and 32-33, page 3-10 and page 52 claim 25. Nielsen et al. also teaches that potassium channel openers are also known to be useful in the treatment of obesity and decreasing weight gain. See page 2 lines 17-21. Nielsen et al. further discloses that the range of effective amounts of active compounds therein to be administered is within the instant range. See page 27 lines 18-20.

Nielsen et al. (WO 9903861) discloses that the active compounds represented by the general formula I therein which has covered the instant elected species are potassium channel openers and useful in a method of treating various diseases of the central nervous system and the cardiovascular system broadly, e.g., hypertension, heart disease, and diabetes. See abstract, page 1 lines 8, 26 and 32-33, page 3-13 and page 52 claim 25. Nielsen et al. also teaches that potassium channel openers are also known to be useful in the treatment of obesity and decreasing weight gain. See page 2 lines 30 to page 3 line 3. Nielsen et al. further discloses that the range of effective amounts of active compounds therein to be administered is within the instant range. See page 30 lines 4-6.

Nielsen et al. does not expressly disclose a method for reducing the consumption of fat-containing food employing the active compounds of Nielsen et al., represented by the general formula I therein. Nielsen et al. does not expressly disclose the instant fat-containing food contains from 10-45 kcal% fat.

Applicant's admission regarding the prior art teaches that the amount of fat-containing food to be consumed or fat intake is tightly associated with risk of obesity,

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hypertension, diabetes, coronary heart disease. See page 1 lines 16-24 and 32-34.

Applicant's admission also teaches that potassium channel openers are also known to be useful in the treatment of obesity and decreasing weight gain. See page 2 line 32 to page 3 line 2.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the active compounds of Nielsen et al., represented by the general formula I therein, in a method for reducing the consumption of fat-containing food, and to employ food herein containing from 10-45 kcal% fat.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the active compounds of Nielsen et al., represented by the general formula I therein, in a method for reducing the consumption of fat-containing food since the active compounds of Nielsen are known to be potassium channel openers and are therefore known to be useful in a method of treating various diseases of the central nervous system and the cardiovascular system broadly, e.g., hypertension, heart disease, diabetes and obesity, and decreasing weight gain. Moreover, since the amount of fat-containing food to be consumed or fat intake is well known to be tightly associated with risk of obesity, hypertension, diabetes, and coronary heart disease according to the prior art, one of ordinary skill in the art would have reasonably expected that the active compounds of Nielsen would have beneficially therapeutical effect on reducing the consumption of fat-containing food. Additionally, it is well known that fat-containing food may contain from 10-45 kcal% fat. Therefore, one having ordinary skill in the art at the time the invention was made would have been

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motivated to employ any fat-containing food containing from 10-45 kcal% fat since it is considered well within the skill of artisan, involving merely routine skill in the art.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

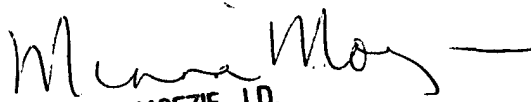
In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
January 4, 2002


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